

Attorney Docket No.: BIG-101  
Appl. Ser. No.: 10/751,405

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**REMARKS**

Applicant submits that the present amendment is fully responsive to the Office Action dated September 7, 2005 and, thus, the application is in condition for allowance.

By this reply, claims 1, 5, 11, 12, 16, 22, 23 and 32 are amended; and claims 33-47 are newly added. Claims 1-47 remain pending. Of these, claims 1, 12 and 23 are independent. An expedited review and allowance of the application is respectfully requested.

In the outstanding Office Action, claims 5 and 16 were rejected under 35 U.S.C. § 101 because it was asserted that the claimed invention is directed to non-statutory subject matter. Although not necessarily agreeing with this assertion, the claims have been amended as suggested in the Office Action to expedite the prosecution of this application.

In the outstanding Office Action, claims 11, 22 and 32 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because of an asserted inclusion of an improper Markush group. Although not necessarily agreeing with this assertion, the claims have been amended as suggested in the Office Action to expedite the prosecution of this application.

In the outstanding Office Action, claims 1-5, 9-16, 20-25, 27 and 31-32 were rejected under 35 U.S.C. § 102(b) as being anticipated by Normann (U.S. Pat. No. 3,974,825). It is asserted that Normann discloses remote electrical monitoring of gas activated blood pumps that are employed outside or inside of the body of a human. Further, it is asserted that particular features recited in the dependent claims are anticipated by Normann. Applicant respectfully traverses.

Neither Normann, nor any other related art of record, alone or in combination, disclose or fairly suggest the present invention as recited in the pending claims. Independent claims 1, 12 and 23 have been presented which clearly and fairly distinguish the present invention from that

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of the art of record. They have support in the original application and claims as filed and contain no new matter. To the extent that the prior rejection is deemed to be applicable to the newly presented and pending claims, they are respectfully traversed.

For example, the present invention recites a device or method which includes a low-profile, non-rigid housing. Such housing ensures that the device is more easily implantable in various positions inside the body, particularly in pediatric patients, in whom space is extremely limited. The unique geometry of the present invention allows for the implantation of the device into spaces where Normann's device would be too bulky. Furthermore, Normann's device as shown in Figure 1 must necessarily include a rigid housing for the metallic films 26 and 28 to properly form a capacitor. In fact, this capacitor formed at the gas chamber surface 26/28 should remain fixed (and not move) for the reference capacitance to remain constant. If the surface of the gas chamber moved, then the capacitance measurements would be skewed and deemed meaningless. Thus, it is necessary for the gas chamber surface to be rigid and inflexible in order for the Normann invention to function as indicated.

Additionally, the Normann device is bulky, even being described as a "dome," which indicates a large and rigid bulky structure. In the case of pediatric patients, such a large, domed structure would not be efficient enough to handle low volume flows, as would be needed in such a case. Thus, the very shape of the Normann device limits its functional use, if any.

Thus, for at least the reasons set forth herein, the present invention as recited in the pending claims should be deemed allowable and the application should be advanced to issue.

In the outstanding Office Action, claims 6-8, 17-19, 26 and 28-30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Normann. It is asserted that Normann discloses essentially the present invention as recited in the claims but for the attachment means for the

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blood pump to the vasculature. It is then asserted that it would have been obvious to modify the attachment as taught by Normann to result in the present invention. It is further alleged that it would have been obvious to modify the maximum volume of the blood chamber, deeming it as routine skill in the art. Thus, it is concluded that Normann obviates the present invention as recited in the claims. Applicant respectfully traverses.

Neither Normann, nor any other related art of record, alone or in combination, disclose or fairly suggest the present invention as recited in the pending claims. Independent claims 1, 12 and 23 have been presented which clearly and fairly distinguish the present invention from that of the art of record. They have support in the original application and claims as filed and contain no new matter. To the extent that the prior rejection is deemed to be applicable to the newly presented and pending claims, they are respectfully traversed.

Dependent claims 2-11, 13-22 and 24-47, which depend on claims 1, 12 and 23, are also allowable for at least the reasons set forth above with respect to the independent claims. Additionally, since Normann neither recites nor suggest the limitations of the dependent claims, there is no motivation, other than Applicant's own invention, to create elements or modify Normann to result in the present invention. Normann makes no mention of attachment techniques and makes no mention of the unique volume capabilities of the present invention. Thus, the present claims cannot be obviated by Normann and should be deemed allowable.

In the outstanding Office Action, claims 6-8, 17-19, 26 and 28-30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Normann in view of Giambruno (U.S. Pat. No. 6,669,726). It is asserted that Normann discloses essentially the present invention as recited in the claims but for maximum volume of the blood chamber. It is further alleged that it would have been obvious to modify the maximum volume of the blood chamber taught by Giambruno

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in order to modify the blood pump to meet specific patient's needs. Thus, it is concluded that Normann in view of Giambruno obviates the present invention as recited in the claims. Applicant respectfully traverses.

Neither Normann nor Giambruno, nor any other related art of record, alone or in combination, disclose or fairly suggest the present invention as recited in the pending claims. Independent claims 1, 12 and 23 have been presented which clearly and fairly distinguish the present invention from that of the art of record. They have support in the original application and claims as filed and contain no new matter. To the extent that the prior rejection is deemed to be applicable to the newly presented and pending claims, they are respectfully traversed.

Dependent claims 2-11, 13-22 and 24-47, which depend on claims 1, 12 and 23, are also allowable for at least the reasons set forth above with respect to the independent claims. Giambruno teaches an artificial heart with blood volumes that are within its range because of its particular design. In no way can the blood volume teachings of Giambruno be applicable to the blood pump monitoring device of Normann because their shape, geometries and functions are completely different. Furthermore, the smaller volume recitations and abilities of the present invention, as recited in the claims, are possible because the present invention is implantable into pediatric patients, who need smaller volumes. As discussed above, Normann is not applicable to pediatric uses because of its cumbersome shape. Thus, it would be wholly impractical or inoperable at such small volumes. Thus, the present claims should be deemed allowable.

New claims 33-47 are presented which recite additional unique features of the present invention. These claims contain no new matter and support for the features may be found in the original specification and drawings, for example, paragraphs 21, 28, 42 and Figure 3.

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If any fees are associated with the entering and consideration of this preliminary amendment, please charge such fees to our Deposit Account 50-2882.

As all of the outstanding rejections have been traversed and all of the claims are believed to be in condition for allowance, Applicant respectfully requests issuance of a Notice of Allowance. If the undersigned attorney can assist in any matters regarding examination of this application, Examiner is encouraged to call at the number listed below.

Respectfully submitted,

Date: 30 November 2005

  
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